REMARKS

A Petition for Extension of Time is being concurrently filed with this Amendment. Thus, this Amendment is timely filed.

Applicant respectfully requests the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 1-9 are currently pending in the present application. The Office Action is non-final. Claims 1-4 and 6-8 have been amended without prejudice or disclaimer. No new matter has been added by way of the amendment, because the amendments are supported by the present specification. Applicant has amended claim 1 to incorporate claim 5. Claim 5 has been cancelled without prejudice or disclaimer. The amendments further define and clarify the structure of the present invention and have support within the present specification. Claim 9 is new and has support within the present specification at pages 14 to 15.

Based upon the above considerations, entry of the present amendment is respectfully requested.

Issues Regarding Information Disclosure Statement (IDS)

The Examiner states that the IDS filed January 13, 2006 fails to comply with the provisions of 37 C.F.R. § 1.97 and MPEP § 609 because there is no translation of JP-11-501950 in full or abstract form.

The IDS mentioned above notes that JP-11-501950-A corresponds to WO 97-/25066-A1, which was considered by the Examiner.

Applicants respectfully request reconsideration on the USPTO part, and that the same reference be initialed (on the earlier submitted SB-08 form) by the Examiner, and that the same be returned to the Offices of the Undersigned.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 5 stands rejected under *35 U.S.C. § 112, second paragraph*, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner states that claim 5 is indefinite since it is drawn to placebo granules containing "no pharmaceutically active substance."

Applicants amended claim 1 to incorporate "placebo granules" from claim 5 and subsequently cancelled claim 5 without prejudice or disclaimer. The amendment to claim 1 obviates the present rejection.

Claims 6 stands rejected under *35 U.S.C. § 112, second paragraph*, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

The Examiner asserts that claim 6 is drawn to an intended use which was further limited by reciting viscosity of a different product than the one claimed. Applicants respectfully request withdraw of the rejection, based on the amendments made herein to pending claim 6, which Applicants submit obviate the outstanding rejection.

Claims 1-8 stand rejected under *35 U.S.C. § 112, second paragraph*, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

The Examiner states that the claims are drawn to a preparation "capable of being administered through an NG tube by dispersing in water before administration" and that this is an intended use, which does not have patentable weight in a product claim.

Applicants have amended claim 1, without prejudice or disclaimer, to remove "capable of being" and thus obviates the present rejection.

Applicants respectfully request reconsideration and subsequent withdrawal of all the above rejections.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-5 and 7-8 stand rejected under *35 U.S.C. § 102(b)* as anticipated by **Depui *et al.***, WO 97/25066 (hereinafter "Depui *et al.*").

Claims 1-5 and 7-8 stand rejected under *35 U.S.C. § 102(b)* as anticipated by **Ukai *et al.***, U.S. Patent Application No. 2002/0039597 (hereinafter "Ukai *et al.*").

Reconsideration and withdraw of each of the above rejections is respectfully requested based on the amendments made herein to the pending claims, and the following considerations.

Claim 5 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claim 5.

Legal Standard for Determining Anticipation

For anticipation under 35 U.S.C. §102, the reference "must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." (MPEP §706.02, Rejection on Prior Art [R-1]). The Federal Circuit has held that prior art is anticipatory only if every element of the claimed invention is disclosed in a single

item of prior art in the form literally defined in the claim. *See Jamesbury Corp. v. Litton Indus. Products*, 756 F.2d 1556, 225 USPQ 253 (Fed. Cir. 1985); *see also Atlas Powder Co. v. du* Pout; 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *American Hospital Suppl v. Travenol Labs*, 745 F.2d 1, 223 USPQ 577 9 (Fed. Cir. 1984).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*See, Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Distinctions Over the Cited Art

The claimed invention preparation is directed to a granule preparation which is obtained by coating seeds with a pharmaceutically active substance, and more specifically by containing therein (i) active granules containing a pharmaceutically active substance, (ii) placebo granules and (iii) a thickening agent.

Placebo granules are contained in the claimed granule preparation as an extender to improve handling of the invention granule preparation when administered. Improvement in view of a quick dispersion in water for use, good viscosity and fluidity within the granule preparation of the claimed invention is an unexpected improvement.

Rejection of claims 1-5 and 7-8 based on Depui et al.

The Examiner suggests that all the critical elements are taught by Depui *et al.*, including dosage forms comprising proton pump inhibitors, bases (antacid agents), alginates, thickeners, polymers (including enteric polymers) and other pharmaceutical excipients to form multilayered tablets, sachets and multiple unit tableted dosage forms (*See* Office Action dated August 30, 2007, page 4 to 5, hereinafter "Office Action"). The Examiner also suggest that this also includes the multiple unit dosage form which is to be dispersed in liquid and can be given to patients with swallowing disorders or to pediatric patients. Applicants respectfully traverse.

Depui *et al.* shows a tablet obtained from an enteric coated pellet containing a proton pump inhibitor, coated on a seed, a dry mixture or alginate containing an acid-suppressing agent, a lubricant and an excipient, page 19, line 22. The components may be separated between different layers.

The Examiner seems to consider that additives such as a base, alginic acid, microcellulose, a buffer, a lubricant and an excipient are placebo granules even in the form of molecules.

Applicants respectfully disagree. In Depui *et al.*, additives are used just for tabletting, that is, a tablet-forming excipient. The present invention comprises placebo granules as an extender for the active granules and for improved handling upon administration. The reference fails to show the addition of an extender as discussed above. Thus, because of the lack of disclosure of all features as instantly claimed, the rejection in view of Depui *et al.* is overcome.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

Rejection of claims 1-5 and 7-8 based on Ukai et al.

The Examiner suggests that Ukai *et al.* teach all the critical elements of the present invention. The Examiner also suggests that this includes proton pump inhibitors, bases, thickeners, polymers (including enteric polymers) and other pharmaceutical excipients that are formed into tablets soluble or rapidly degradable (dispersible) in water or gastric acid (*See* Office Action, page 6 to 7). Although the materials are screened with a 24 mesh screen, the particle sizes are 840 microns or less, which the Examiner asserts that this is covered by Ukai *et al.*

Additionally, the Examiner further suggests granules are combined with crospovidone, bases and granules not containing the proton pump inhibitors (i.e., "placebo") and other excipients to be compressed into a tablet. In addition, the Examiner suggests that Tables 6-13 and examples 28-29 fulfill the claims. Again, Applicants respectfully traverse.

Ukai *et al.* shows a tablet, quickly dissolved, containing PPI, a base, a thickening agent, a polymer and an excipient. The reference tablet is prepared by wet-mixing PPI, a base, mannitol and HPC, which are then subsequently granulated.

Ukai *et al.* fails to show a structure obtained by coating seeds with a pharmaceutically active substance. This is exemplified in the referenced Tables 6-13 (examples 4-9) and examples 28-29. The Table and examples reference by the Examiner do not teach this element.

Thus, because of the lack of disclosure of all features as instantly claimed, the rejection in view of Ukai *et al.* is overcome.

Applicants respectfully request reconsideration and withdrawal of the present rejection.

The Depui *et al.* and Ukai *et al.* references cannot anticipate the present claims because the cited references fail to disclose all instantly claimed features. *See, e.g., Hybritech, Inc. v.*

Monoclonal Antibodies, Inc., 231 USPQ 81 (Fed. Cir. 1986) ("for prior art to anticipate under § 102 it has to meet every element of the claimed invention"), *cert. denied*, 480 U.S. 947, 107 S. Ct. 1606 (1987).

In light of the above, Applicants respectfully request reconsideration and subsequent withdrawal of the above rejections.

Rejections Under the Obviousness-Type Double Patenting Doctrine

Claims 7 and 8 stand provisionally rejected under the judicially created doctrine against obviousness-type double patenting as being unpatentable by co-pending application No. 10/938554. Applicants respectfully traverse the rejection as hereinafter set forth.

The Examiner is respectfully requested to follow the procedure that is described in M.P.E.P. § 804(I)(B)(1), and reads as follows:

> *If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.*
>
> *If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.*

Accordingly, the Examiner is respectfully requested to issue a Notice of Allowance in this case and to address any possible double patenting issues in the co-pending applications.

In view of the above amendments, Applicants believe the pending application is in condition for allowance.

Additional Considerations

For completeness, it is also noted that neither of the cited art references (i.e., Depui *et al.* nor Ukai *et al.*) provide any teaching or disclosure that would allow one of ordinary skill in the art to arrive at the instant invention as claimed. More particularly, one of ordinary skill in the art, upon considering the disclosures of each of Depui *et al.* and Ukai *et al.*, would find no reason or rationale in the cited art to arrive at the instant invention as claimed. As such, it follows that neither of the cited art references' disclosures can serve as a proper basis for rejecting any of instantly pending claims 1-4 and 6-9 under the provisions of 35 U.S.C. § 103(a). Any contentions of the USPTO to the contrary must be reconsidered at present.

CONCLUSION

In view of the above amendment and comments, Applicants respectfully submit that each of instantly pending claims 1-4 and 6-9 are in condition for allowance. As such, the Examiner is respectfully requested to issue a Notice of Allowance indicating that such claims are allowed and patentable under the provisions of Title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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